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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/544,167	07/29/2005	Amir Genosar	5114-00004	7745

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EXAMINER
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CAMPBELL, VICTORIA P

ART UNIT	PAPER NUMBER
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4123

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10/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/544,167

Applicant(s)

GENOSAR, AMIR

Examiner

Victoria P. Campbell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 July 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/29/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This is the initial Office Action based on the 10/544,167 application filed July 29, 2005.

Claims 1-28 as amended July 29, 2005 are currently pending and considered below.

#### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. The citation of references on pages 1-4 of the specification is improper and the examiner has not considered those references as specified above.

#### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Fig. 4D #41. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet,

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even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if

the required "Sequence Listing" is not submitted as an electronic document on compact disc).

4. The abstract of the disclosure is objected to because of the following minor informalities:

Throughout the specification, the phrase "liquid filled" (first instance line 5 of the abstract) needs to be changed to --liquid-filled-- to be grammatically correct.

Line 6 reads "controlled chamber" and should be changed to --control chamber--.  
Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities:

In the first paragraph of CROSS-REFERENCE TO RELATED APPLICATIONS, provided by preliminary amendment, lines 2-3 currently read "which international application was published on August 12, 2004," and should be amended to read --which was published on August 12, 2004,--.

In the first paragraph of DESCRIPTION OF PRIOR ART, the second line reads "delivery of drugs and or biologically active materials" and should be changed to read --delivery of drugs and/or biologically active materials--.

6. The use of the trademarks FLOUROPORE and EMFLON have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

***Claim Objections***

7. Claims 1-28 are objected to because of the following informalities: Throughout the claims, the statement "liquid filled" (first instance in line 3 of claim 1) should be changed to --liquid-filled--.

Claim 8, line 2 "coupled in series-" should read -- coupled in series --.

Claim 10 does not end in a period -- . --.

Claim 17 concludes with "electroencephalography, and electrocardiography and combinations thereof" but should read -- electroencephalography, electrocardiography, and combinations thereof --. Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10 and 11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicant claims "an injection site" which was previously described by the applicant in the specification on page 6, paragraph 3, line 2 as "an injection site in the body of the recipient". As a result, both claims 10 and 11 claim a portion of the human body and are therefore non-statutory.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitations "the drug infusion rate" in line 5, "the volume of liquid" in line 7, and "the drug in said reservoir" in line 8. There is insufficient antecedent basis for these limitations in the claim.

Claim 4 recites the limitations "said chambers" in line 2 and "the displacement caused" in lines 2-3. There is insufficient antecedent basis for these limitations in the claim.

Claims 10 and 11 recites the limitation "said injection site" in line 1 of each of the claims. There is insufficient antecedent basis for this limitation in the claims.

Claim 19 recites the limitation "the gas production". There is insufficient antecedent basis for this limitation in the claim.

Claim 28 provides for the use of the drug delivery infusion device as described in claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

***Allowable Subject Matter***

11. Claims 1-9 and 12-28 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action. The following is a statement of reasons for the indication of allowable subject matter: The mechanism of action employing depletion of a liquid in a control chamber in order to simultaneously decrease the quantity of liquid in a coupled drug dispensing chamber is neither disclosed nor made obvious in the prior art.

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent Application Publication No. 2002/0173769 to Gray et al discloses a "tube set" as disclosed in claim 27 to deliver the fluid in question from the drug delivery device to the patient. US Patent No. 6,186,982 to Gross et al also discloses a method by which the changes in external temperature and pressure can be accounted for when using gas generation as the means for expelling the drug at a constant rate. US Patent No. 5,290,240 issued to Horres, Jr. which details a dispensing assembly containing both a permanent unit and a disposable portion. US Patent No. 5,242,565 to Winsel details the use of electrodes to generate and release a gas from an aqueous electrolytic cell. US Patent No. 5,858,001 to Tsals et al discloses a gas-generating means using the reaction of citric acid and sodium bicarbonate, which also be used in the invention as disclosed. US Patent No. 5,354,264 to Bae et al discloses a device which directly uses gas pressure derived from the electrolysis of water into free

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oxygen and hydrogen to drive drugs into the patient. The rate is also disclosed to be controlled by a biomedical control system, as disclosed by the applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victoria P. Campbell whose telephone number is 571-270-5035. The examiner can normally be reached on Monday-Thursday, 7-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VPC

  
JOSEPH DEL SOLE  
SUPERVISORY PATENT EXAMINER

10/17/07